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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/840,197	<b>Applicant(s)</b> WIDRA, ABE	
	<b>Examiner</b> Sandra Saucier	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 9-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

DETAILED ACTION

Claims 1-3, 9-20 are pending. Claims 1-3 are considered on the merits. Claims 9-20 are withdrawn from consideration as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

INDEFINITE

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 reads "a physiologically balanced electrolyte solution". This does not appear to be a term of art. In what respect is the electrolyte solution physiologically balanced? Osmotically? With respect to amino acid concentrations? With respect to the types of electrolytes? As compared to rabbit or human physiology? As compared to the physiology of plasma or serum or blood or interstitial fluid or gastric fluid? Please point to the definition in the specification for clarification of this term.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed, had possession of the claimed invention.

There does not seem to be either a definition or literal support in the specification for the new insertion "physiologically balanced electrolyte solution".

***Claim Rejections - 35 USC § 102***

Claims 1-3 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ewald *et al.* [IDS].

Ewald *et al.* disclose a composition comprising a soluble component of keratin obtained by hydrogen peroxide hydrolysis in sterile saline.  $\alpha$ -keratose would at least be one component of the solution disclosed by Ewald *et al.*

Sterile saline is considered to be a physiologically balanced electrolyte solution

since sterile saline is 0.14M which is the physiological electrolyte concentration of plasma and has been used extensively in the prior art as a carrier for intravenously administered drugs.

***Response to Arguments***

Applicant's arguments filed 11/21/03 have been fully considered but they are not persuasive.

Applicant argues that it is not necessarily true that  $\alpha$ -keratose would be a component of the composition of Ewald *et al.* since they never demonstrated the sulfur-bearing alpha-linked amino acid chains from the complex mixture of oxidized, sulfonated peptides in their soluble hydrolyzate. Please note that it is applicant who must demonstrate the absence of  $\alpha$ -keratose in the cited composition. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' composition differs and, if so, to what extent from the composition discussed in the reference. Accordingly, it has been established that the prior art composition, which been produced from the same source material and shares the property of being used as a plasma extender demonstrates a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty by objective evidence is shifted to applicants.

Merely because an inherent component of a known composition is not disclosed in a reference does not make the known composition patentable. The known composition possesses inherent components which might not be precisely disclosed in the reference.

The composition of Ewald *et al.* is argued to be 84% gamma-keratose, which is toxic. This may be true, however, please note that applicant's composition claim is not closed to further components in the composition, rather the claim language is open "comprising". Thus, the arguments are not commensurate in scope with the claims and are, therefore, not persuasive.

***Conclusion***

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized, cursive script.

Sandra Saucier  
Primary Examiner  
Art Unit 1651  
January 12, 2004